

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and ABBOTT  
RESPIRATORY LLC,

Plaintiffs,

v.

IMPAX LABORATORIES, INC.,

Defendant.

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C.A. No. \_\_\_\_\_

**COMPLAINT**

Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, “Abbott”), by their attorneys, hereby allege as follows:

**NATURE OF THE ACTION**

This is an action for patent infringement of U.S. Patent Nos. 6,080,428 (“the ’428 patent”), 6,129,930 (“the ’930 patent”), 6,406,715 (“the ’715 patent”), 6,469,035 (“the ’035 patent”), 6,676,967 (“the ’967 patent”), 6,746,691 (“the ’691 patent”), 6,818,229 (“the ’229 patent”), and 7,011,848 (“the ’848 patent”), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application (“ANDA”) No. 202149 filed by Impax Laboratories, Inc. with the U.S. Food and Drug Administration (“FDA”) for approval to market 1000 mg / 20 mg niacin extended release / simvastatin tablets, which is a generic version of the 1000 mg / 20 mg form of Abbott’s SIMCOR<sup>®</sup> drug product.

**RELATED ACTIONS**

Abbott has filed several other patent infringement actions currently pending before the Court as described below:

- *Abbott Laboratories & Abbott Respiratory LLC v. Lupin Ltd. & Lupin Pharmaceuticals, Inc.*, No. 09-152-LPS (D. Del.), which relates to ANDA Nos. 90-4446, 90-860, and 90-892 filed by Lupin for approval to market generic versions of NIASPAN<sup>®</sup>, and involves the '930 patent, the '715 patent, the '967 patent, the '691 patent, the '848 patent, the '229 patent, and the '428 patent;
- Consolidated cases *Abbott Laboratories & Abbott Respiratory LLC v. Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc.*, Nos. 10-57-SLR-MPT, 10-302-SLR-MPT, 10-766-SLR (D. Del.), which relate to ANDA No. 200478 filed by Teva for approval to market generic versions of SIMCOR<sup>®</sup>, and involve the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '848 patent, the '229 patent, and the '428 patent, and *Abbott Laboratories & Abbott Respiratory LLC v. Watson Laboratories, Inc. – Florida*, No. 10-373-SLR (D. Del.), which relates to ANDA No. 200601 filed by Watson for approval to market a generic version of SIMCOR<sup>®</sup>, and also involves the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '848 patent, the '229 patent, and the '428 patent;
- *Abbott Laboratories & Abbott Respiratory LLC v. Sun Pharmaceutical Industries Ltd. & Sun Pharma Global FZE*, Nos. 10-112-SLR-MPT, 10-488-SLR (D. Del.), which relate to ANDA Nos. 200484 and 201273 filed by Sun for approval to market generic versions of NIASPAN<sup>®</sup>, and involve the '428 patent and the '035 patent;
- *Abbott Laboratories & Abbott Respiratory LLC v. Sandoz Inc.*, No. 10-538-SLR (D. Del.), which relates to ANDA No. 201403 filed by Sandoz for approval to market a

generic version of NIASPAN<sup>®</sup>, and involves the '429 patent, the '035 patent, and the '229 patent; and

- *Abbott Laboratories & Abbott Respiratory LLC v. Mylan Inc. & Mylan Pharmaceuticals, Inc.*, No. 10-559-SLR (D. Del.), which relates to ANDA No. 201521 filed by Mylan for approval to market a generic version of SIMCOR<sup>®</sup>, and involves the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '848 patent, the '229 patent, and the '428 patent.

### **PARTIES**

1. Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Abbott Respiratory LLC ("Abbott Respiratory") is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Upon information and belief, Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

### **JURISDICTION AND VENUE**

4. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

5. This Court has personal jurisdiction over Impax because, *inter alia*, it is a Delaware corporation.

**PATENTS IN SUIT**

6. Abbott Respiratory is the owner by assignment of the '428 patent, entitled "Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Thereof," which the U.S. Patent and Trademark Office duly and legally issued on June 27, 2000. A true and correct copy of the '428 patent is attached hereto as Exhibit A. The claims of the '428 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '428 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '428 patent.

7. Abbott Respiratory is the owner by assignment of the '930 patent, entitled "Methods and Sustained Release Nicotinic Acid Compositions for Treating Hyperlipidemia at Night," which the U.S. Patent and Trademark Office duly and legally issued on October 10, 2000. A true and correct copy of the '930 patent is attached hereto as Exhibit B. The claims of the '930 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '930 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '930 patent.

8. Abbott Respiratory is the owner by assignment of the '715 patent, entitled "Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique Urinary Metabolite Profiles," which the U.S. Patent and Trademark Office duly and legally issued on June 18, 2002. A true and correct copy of the '715 patent is attached hereto as Exhibit C. The claims of the '715 patent are valid and enforceable. Abbott Laboratories is an

exclusive licensee of the '715 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '715 patent.

9. Abbott Respiratory is the owner by assignment of the '035 patent, entitled "Methods of Pretreating Hyperlipidemic Individuals with a Flush Inhibiting Agent Prior to the Start of Single Daily Dose Nicotinic Acid Therapy to Reduce Flushing Provoked by Nicotinic Acid," which the U.S. Patent and Trademark Office duly and legally issued on October 22, 2002. A true and correct copy of the '035 patent is attached hereto as Exhibit D. The claims of the '035 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '035 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '035 patent.

10. Abbott Respiratory is the owner by assignment of the '967 patent, entitled "Methods for Reducing Flushing in Individuals Being Treated with Nicotinic Acid for Hyperlipidemia," which the U.S. Patent and Trademark Office duly and legally issued on January 13, 2004. A true and correct copy of the '967 patent is attached hereto as Exhibit E. The claims of the '967 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '967 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '967 patent.

11. Abbott Respiratory is the owner by assignment of the '691 patent, entitled "Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique Biopharmaceutical Characteristics," which the U.S. Patent and Trademark Office duly and legally issued on June 8, 2004. A true and correct copy of the '691 patent is attached hereto as Exhibit F. The claims of the '691 patent are valid and enforceable. Abbott Laboratories is an

exclusive licensee of the '691 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '691 patent.

12. Abbott Respiratory is the owner by assignment of the '229 patent, entitled "Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia," which the U.S. Patent and Trademark Office duly and legally issued on November 16, 2004. A true and correct copy of the '229 patent is attached hereto as Exhibit G. The claims of the '229 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '229 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '229 patent.

13. Abbott Respiratory is the owner by assignment of the '848 patent, which bears on its face the title "Hydrophobic Component Free Sustained Release Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor," which the U.S. Patent and Trademark Office duly and legally issued on March 14, 2006. A true and correct copy of the '848 patent is attached hereto as Exhibit H. The claims of the '848 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '848 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '848 patent.

14. Abbott Laboratories is the holder of New Drug Application ("NDA") No 02-2078, by which the FDA granted approval for 500 mg / 20 mg, 750 mg / 20 mg, and 1000 mg / 20 mg strength niacin extended-release / simvastatin tablets, which Abbott markets in the United States under the trade name "SIMCOR<sup>®</sup>." The formulation and dosing of SIMCOR<sup>®</sup> is covered by certain claims of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent. The FDA's official

publication of approved drugs (the “Orange Book”) includes SIMCOR® together with the ’428 patent, the ’930 patent, the ’715 patent, the ’035 patent, the ’967 patent, the ’691 patent, the ’229 patent, and the ’848 patent.

### **INFRINGEMENT BY IMPAX**

15. By letter dated October 13, 2010, (“the Notice Letter”), Impax notified Abbott that Impax had submitted ANDA No. 202149 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of generic niacin extended-release / simvastatin tablets before the expiration of the ’428 patent, the ’930 patent, the ’715 patent, the ’035 patent, the ’967 patent, the ’691 patent, the ’229 patent, and the ’848 patent. Upon information and belief, Impax intends to engage in commercial manufacture, use, and sale of generic niacin extended-release / simvastatin tablets promptly upon receiving FDA approval to do so.

16. By filing ANDA No. 202149, Impax has necessarily represented to the FDA that the components of its generic niacin extended-release / simvastatin tablets have the same active ingredients as those of the corresponding components of SIMCOR®, have the same route of administration, dosage form, and strengths as the corresponding components of SIMCOR®, and are bioequivalent to the corresponding components of SIMCOR®.

17. In the Notice Letter, Impax notified Abbott that its ANDA contained a “Paragraph IV certification” asserting that, in Impax’s opinion, the ’428 patent, the ’930 patent, the ’715 patent, the ’035 patent, the ’967 patent, the ’691 patent, the ’229 patent, and the ’848 patent are invalid and/or will not be infringed by the commercial manufacture, use or sale of its generic niacin extended-release / simvastatin tablets.

18. This Complaint is being filed before the expiration of the forty-five days from the date Abbott received the Notice Letter.

**COUNT I**  
**(INFRINGEMENT OF THE '428 PATENT)**

19. Each of the preceding paragraphs 1 to 18 is incorporated as if fully set forth.

20. Impax's submission of ANDA No. 202149 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '428 patent constitutes infringement of one or more of the claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

21. Upon FDA approval of Impax's ANDA No. 202149, Impax will further infringe the '428 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

22. Upon information and belief, Impax had actual and constructive knowledge of the '428 patent prior to filing ANDA No. 202149 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '428 patent.

23. If Impax's infringement of the '428 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT II**  
**(INFRINGEMENT OF THE '930 PATENT)**

24. Each of the preceding paragraphs 1 to 23 is incorporated as if fully set forth.



25. Impax's submission of ANDA No. 202149 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '930 patent constitutes infringement of one or more of the claims of the '930 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon FDA approval of Impax's ANDA No. 202149, Impax will further infringe the '930 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

27. Upon information and belief, Impax had actual and constructive knowledge of the '930 patent prior to filing ANDA No. 202149 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '930 patent.

28. If Impax's infringement of the '930 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT III**  
**INFRINGEMENT OF THE '715 PATENT**

29. Each of the preceding paragraphs 1 to 28 is incorporated as if fully set forth.

30. Impax's submission of ANDA No. 202149 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '715 patent constitutes infringement of one or more of the claims of the '715 patent under 35 U.S.C. § 271(e)(2)(A).

31. Upon FDA approval of Impax's ANDA No. 202149, Impax will further infringe the '715 patent by making, using, offering to sell, and selling generic niacin extended-

release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

32. Upon information and belief, Impax had actual and constructive knowledge of the '715 patent prior to filing ANDA No. 202149 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '715 patent.

33. If Impax's infringement of the '715 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT IV**  
**INFRINGEMENT OF THE '035 PATENT**

34. Each of the preceding paragraphs 1 to 33 is incorporated as if fully set forth.

35. Impax's submission of ANDA No. 202149 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '035 patent constitutes infringement of one or more of the claims of the '035 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon FDA approval of Impax's ANDA No. 202149, Impax will further infringe the '035 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

37. Upon information and belief, Impax had actual and constructive knowledge of the '035 patent prior to filing ANDA No. 202149 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '035 patent.

38. If Impax's infringement of the '035 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT V**  
**INFRINGEMENT OF THE '967 PATENT**

39. Each of the preceding paragraphs 1 to 38 is incorporated as if fully set forth.

40. Impax's submission of ANDA No. 202149 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '967 patent constitutes infringement of one or more of the claims of the '967 patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon FDA approval of Impax's ANDA No. 202149, Impax will further infringe the '967 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

42. Upon information and belief, Impax had actual and constructive knowledge of the '967 patent prior to filing ANDA No. 202149 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '967 patent.

43. If Impax's infringement of the '967 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT VI**  
**INFRINGEMENT OF THE '691 PATENT**

44. Each of the preceding paragraphs 1 to 43 is incorporated as if fully set forth.

45. Impax's submission of ANDA No. 202149 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '691 patent constitutes infringement of one or more of the claims of the '691 patent under 35 U.S.C. § 271(e)(2)(A).

46. Upon FDA approval of Impax's ANDA No. 202149, Impax will further infringe the '691 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

47. Upon information and belief, Impax had actual and constructive knowledge of the '691 patent prior to filing ANDA No. 202149 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '691 patent.

48. If Impax's infringement of the '691 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT VII**  
**INFRINGEMENT OF THE '229 PATENT**

49. Each of the preceding paragraphs 1 to 48 is incorporated as if fully set forth.

50. Impax's submission of ANDA No. 202149 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '229 patent constitutes infringement of one or more of the claims of the '229 patent under 35 U.S.C. § 271(e)(2)(A).

51. Upon FDA approval of Impax's ANDA No. 202149, Impax will further infringe the '229 patent by making, using, offering to sell, and selling generic niacin extended-

release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

52. Upon information and belief, Impax had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 202149 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '229 patent.

53. If Impax's infringement of the '229 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT VIII**  
**INFRINGEMENT OF THE '848 PATENT**

54. Each of the preceding paragraphs 1 to 53 is incorporated as if fully set forth.

55. Impax's submission of ANDA No. 202149 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '848 patent constitutes infringement of one or more of the claims of the '848 patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon FDA approval of Impax's ANDA No. 202149, Impax will further infringe the '848 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

57. Upon information and belief, Impax had actual and constructive knowledge of the '848 patent prior to filing ANDA No. 202149 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '848 patent.

58. If Impax's infringement of the '848 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**PRAYER FOR RELIEF**

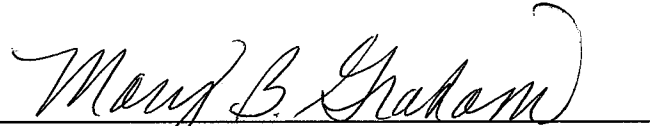
WHEREFORE, Abbott prays that this Court grant the following relief:

- a) A judgment that one or more claims of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent are infringed by Impax's submission of ANDA No. 202149, and that Impax's making, using, offering to sell, or selling in the United States, or importing into the United States, of generic niacin extended-release / simvastatin tablets will infringe the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent;
- b) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 202149 shall be a date which is not earlier than the latest expiration date of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;
- c) An order permanently enjoining Impax, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic niacin extended-release / simvastatin tablets until after the latest expiration date of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

d) Damages or other monetary relief to Abbott if Impax engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of generic niacin extended-release / simvastatin tablets prior to the latest expiration date of the '428 patent, the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled.

e) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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